

Recommendations from Immune Correlate Break out Group (March 2004 group A strep Vaccine Workshop)

1. Move ahead to **human clinical trials** while utilizing existing animal models for functional mucosal immunity, systemic immunity and antigen-specific toxicity/safety to correlate with human trials.
2. In human trials, define antigen specific **immune responses*** that are associated with clinical protection
3. Agreement on feasible validated standardized operating procedures to measure antigen specific **immune correlates*** of protection in mucosal and systemic immunity.
4. Preclinical and translational research to assess risk for RHD, AGN

***Quantitative and functional assays to assess humoral and cellular immune function, for example:**

ELISA

Opsonophagocytosis

Active and passive animal efficacy assays

Neutralization of adherence on human cells

Neutralization of enzyme activity

Tetramer screening for T cell precursors

T cell functional assays

Other recommendations:

- *Encourage investigation of multicomponent vaccine
- *Explore novel vaccine delivery/formulation vehicles to maximize efficacy